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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,947	08/07/2006	Untack Lee	44352-0009-00-US	8890
23973 7590 07/21/2009 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996				
			EXAMINER	
CUTLIFF, YATE KAI RENE				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
07/21/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,947

Applicant(s)

LEE ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1 - 11 are pending.
Claims 1 – 11 are rejected.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 28, 2009 has been entered.

Priority

3. Receipt is acknowledged of translation of foreign priority papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file in accordance with 37 CFR 1.55. (MPEP 201.15).

Response to Arguments

4. Applicant's arguments, see pages 2-4, filed May 28, 2009, with respect to the rejection(s) of claim(s) 1-11 under 35 USC 103(a) have been fully considered and are persuasive in view of the priority date. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Krumhar (US 6,432,453) in view of Koike et al. (WO 2002/11552 A2) and further in view of Cain et al. (US 6,184,009).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). Further, that the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that,

as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117.

Claim 1 recites "wherein about 5-98% of the fatty acids contained in the total glycerides are a conjugated linoleic acid (CLA). Additionally, claim 11 states that 75% of the fatty acids contained in the total triglycerides are a CLA.

Examiner can not find support for these limitation in the body of the originally filed Application. The specification, page 5, lines 18-19 states; "the ratio of conjugated linoleic acid (CLA) to fatty acids contained in the total glycerides is 5-98%".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krumhar (US 6,432,453) in view of Koike et al. (WO 2002/11552 A2) and further in view of Cain et al. (US 6,184,009).

11. The rejected claims cover, inter alia, an oil composition comprising about 80-95% by weight of diglycerides, wherein about 5-98% of the fatty acids contained in the total triglycerides are a conjugated linoleic acid (CLA). The dependent claims disclose the weight percentage of the remaining portion of the oil composition; the isomeric forms of the CLA; the animal and vegetable oils used to obtain the CLA; and the uses for the CLA composition. Additionally, that 75% of the fatty acids contained in the total triglycerides are CLA.

12. Krumhar teaches compositions comprising glycerol esters of conjugated linoleic acid, wherein the glycerol esters are selected from the group consisting of monoglyceride, diglyceride, triglyceride and mixtures thereof (abstract, column 4, lines 7-8). The CLA esters of Krumhar can be used in dietary supplements, foods and drugs. (see column3, lines 65-67). Also, Krumhar teaches various methods of preparing the diglycerides of conjugated linoleic acid such as transesterification, or via acid by reacting CLA and glycerol from a mixture of cis-9, trans-11 CLA and trans-10,

cis12 CLA (see column 5, lines 25-41). Further, Krumhar discloses that the CLA glycerol ester is provided in the dietary supplements from about 32% to about 91% by weight of the conjugated linoleic acid (see claim 1), and that the glycerol ester is selected from the group consisting of monoglyceride, diglyceride triglyceride and mixtures thereof (see claim 2). Krumhar discloses that the composition can contain glycerol. (see column 5, lines 63-64, & Table 1).

13. The difference between Krumhar and Applicant's claimed invention is the following: specific percentages of the diglyceride; the oil source of the CLA; the specific foods that may include CLA; the specific form of the pharmaceutical containing CLA and the various isomeric formations of CLA in the triglyceride.

14. However, Koike et al. discloses a oil/fat composition teaches a fat composition comprising 60-100% of a diglyceride (DG) (see abstract). Table 1 teaches examples where the DG is present in an amount greater than 85%, triglyceride (TG) is 13.4-15.6, monoglyceride (MG) is 1.1-3.1 and fatty acid C18:2 (w6)(c-10, c-12) is 16.4-17.5. Table 5 teaches another example of DG greater than 85% and that the conjugated amount is 16.4% (c-19, c-12). Further, the oil/fat composition of Koike et al. prepares the oil composition from natural oils such as linseed oil and rapeseed. (see Composition 2 page 17). The composition of Koike et al. can be used in foods such as, dressings, mayonnaise, whipped cream, ice cream, margarine, spread, butter cream and edible oils (see page 11, lines 13-22; page 12, line 13). Also, when used in a pharmaceutical composition, it can be in the form of a powder, capsule, tablet or liquid. (see page 15, lines 19-20). Furthermore, it can be added to feed. (see page 16, line 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Krumhar in view of Koike et al. Krumhar generically teaches a composition of mono-, di- and tri-glycerides including CLA in the percentage instant claimed, while Koike et al. teaches the percentage of the diglyceride in such a composition. One of ordinary skill in the art would have been motivated to combine since all teach fat compositions comprising a mixture of glycerides including diglycerides for food, pharmaceutical and feed additive with Koike et al. teaching the percentage of diglycerides and Krumhar teaches the cis-9, trans-11 CLA and trans-10, cis12 CLA mixture contains diglycerides. One of ordinary skill in the art would have a reasonable expectation of success in formulating the composition of 'Krumhar in view of Koike et al since both teach the same components in a fat composition for food supplementation and pharmaceuticals. The product of Krumhar containing CLA diglycerides could easily be made by the skilled artisan in the amounts instant claimed using a known techniques and preferred ranges taught by Koike et al.

15. With regard to the oil source of the CLA, and the various isomeric formations of CLA in the triglyceride the Examiner turned to the teachings of Cain et al. The Cain et al. reference teaches a process for preparing a material containing the geometrical isomers of conjugated linoleic acid moieties in specific weight ratios. The starting material is fish oil or vegetable oil and the products may be blended with complementary fat, used as food or food supplements or in pharmaceutical compositions. (see abstract). Further, Cain states the following in column 1, at lines 19-26.

Because of cis/trans-isomerism above CLA's can contain 8 different isomers, i.e. cis⁹-cis¹¹; cis⁹-trans¹¹; trans⁹-cis¹¹; trans⁹-trans¹¹; cis¹⁰-cis¹²; cis¹⁰-trans¹²; trans¹⁰-cis¹² and trans¹⁰-trans¹². From those isomers the cis⁹-trans¹¹ and trans¹⁰-cis¹² are the most abundant, while their concentrations are about equal. It is generally believed, that those two most abundant isomers are responsible for the beneficial effects of the compositions, containing CLA's.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have an oil composition produced from natural products having conjugated linoleic acid (CLA) with varied isometric structures, as suggested by Cain et al., which states that, CLA's have 8 different isomeric forms, and be able to produce such an oil composition since Cain suggest a process for preparing the geometric isomers of CLA; and produce the instant invention. One of ordinary skill in the art would have been motivated to do this because CLAs are suggested by Krumhar and Cain et al. for use in foods, food supplements and pharmaceuticals (drugs).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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